



BILLING CODE: 4410-09-P

**DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION**

**HENRI WETSELAAR, M.D.
DECISION AND ORDER**

On September 27, 2011, I, the Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Henri Wetselaar, M.D. (Respondent), of Las Vegas, Nevada. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration as a practitioner, and the denial of any application to renew or modify his registration, on the ground that Respondent's "continued registration is inconsistent with the public interest." Show Cause Order at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

The Show Cause Order alleged that from April through August 2010, law enforcement personnel performed eight undercover visits during which Respondent issued prescriptions without "a legitimate medical purpose" and acted outside of the "usual course of professional practice." *Id.* at 1-2 (citing 21 CFR 1306.04(a)). More specifically, the Order alleged, *inter alia*, that Respondent prescribed increasing doses of oxycodone, a schedule II controlled substance, at the request of the undercover officers and performed either "cursory or no medical examinations"; "offered large doses of alprazolam to [an] undercover officer," notwithstanding that the officer "did not complain of any medical condition warranting such medication"; "varied [his] office fee depending on the type of controlled substance [he] prescribed"; and "allowed the undercover officers to dictate to [him] what controlled substances they preferred to receive, rather than prescribe based on [his] own medical judgment." *Id.* at 2.

The Show Cause Order further alleged that a medical expert had “reviewed more than 200 patient files obtained from [Respondent’s] office” and found that he “consistently prescribed large amounts of oxycodone and alprazolam without adequate examination and documentation to support such prescribing.” Id. Finally, the Show Cause Order alleged that following the August 2010 execution of a search warrant at his office, “prescription monitoring data has revealed that [Respondent] continue[s] to prescribe large amounts of oxycodone 30mg tablets, hydrocodone and alprazolam.” Id.

On September 29, 2011, the Order, which also notified Respondent of his right to request a hearing on the allegations, or to submit a written statement in lieu of a hearing, the procedures for electing either option (including that he file his request for a hearing or his written statement within 30 days of receipt of the Order), and the consequences for failing to do either, was served on him.¹ GX 3. On November 9, 2011, Respondent, through his counsel, submitted a letter to the Hearing Clerk, Office of Administrative Law Judges, requesting an extension of forty-five days to respond to the allegations. GX 4.

Thereafter, the Government moved to terminate the proceeding on the grounds that Respondent had neither requested a hearing nor timely filed a request for an extension to request a hearing. GX 5, at 1. The Government also argued that Respondent had not established “good cause” for his untimely filing. Id. at 3.

Upon reviewing the motion, the ALJ ordered Respondent to respond to the Government’s motion. GX 6. Thereafter, Respondent’s counsel submitted a letter stating that he “ha[d] voluntarily chosen to forego his right to file a Request for a Hearing” and respond to the Show Cause Order. GX 7. The ALJ then found that Respondent had withdrawn his request for a

¹ According to the Government, the Order was served on Respondent when he was arrested and taken into custody. GX 5, at 3.

hearing, granted the Government's motion and ordered that the proceeding be terminated. GX 8, at 1-2. Several months later, the Government forwarded the investigative record to this office with its request for Final Agency Action.

Having reviewed the record, I adopt the ALJ's finding that Respondent has withdrawn his request for a hearing. I further hold that the evidence with respect to factors two and four supports a finding that Respondent has committed acts which render his registration "inconsistent with the public interest." 21 U.S.C. 824(a)(4). I make the following factual findings.

FINDINGS

Respondent is the holder of DEA Certificate of Registration BW5180372, which, prior to the issuance of the Order of Immediate Suspension, authorized him to dispense controlled substances in schedules II through V at the registered location of New Amsterdam Medical Group, 4525 S. Sandhill Road, Suite 107, Las Vegas, Nevada. GX 1. Respondent's registration was due to expire on May 31, 2011. *Id.* However, on April 5, 2011, Respondent submitted a renewal application. Because Respondent's application was timely filed under the Agency's rule, Respondent retains a registration, albeit one that has been suspended. See 5 U.S.C. 558(c). Accordingly, there is both a registration and an application to act upon.

The Undercover Visits

On April 6, 2010, a DEA Task Force Officer (TFO 1) visited Respondent complaining of pain in his right shin which occurred only when he ran but that he had for six months. GX 11, at 59. During the visit, Respondent asked TFO 1 what he thought caused the pain ("probably running") and TFO 1's vital signs were taken. *Id.* at 60. Moreover, the transcript of the visit suggests that Respondent performed a physical exam during which he listened to the TFO's heart

and lungs, palpated his abdomen, and examined his lower leg. Id. at 61-62. Also, upon examining his leg, the TFO stated that he felt tenderness in his leg, with Respondent and his assistant concluding that he had tenderness in the middle of his tibia. Id. at 64. Respondent also asked the TFO about his general health, whether he smoked or drank alcohol (and upon the TFO's stating that he drank, asked the TFO how often he drank), his employment and marital status, and whether the TFO had ever been hospitalized. Id. at 61-67.

Respondent then asked the TFO what medications worked best for his pain; the TFO replied that he "would like to get, if I could get Percocet or Oxy." Id. at 67. Respondent asked the TFO if he had tried Percocet before; the TFO said he had and that he used it before he ran. Id. Respondent then asked the TFO how many times a day he had taken Percocet when he used it; the TFO stated "twice." Id. Respondent then agreed to give Percocet to the TFO and to prescribe it three times a day. Id.

Respondent's assistant asked the TFO if there was any other medication he took "for anxiety or Xanax." Id. The TFO replied that he was "always stressed, but no, I don't take anything. I mean, I got some in the past, but." Id. Respondent's assistant then asked if that helped him, and laughing, the TFO replied: "Yeah. Everything helps. Everything helps. Can I get some Xanax?" Id. Respondent replied: "yeah, but that's why he mentioned it. We'd be happy to write some Xanax for you, if you liked it then." Id.

The TFO then asked if he could get some testosterone cream. Id. at 68. However, Respondent's assistant explained that "we don't do that type of practice" and "we'd have to run some blood work" and "we just can't give it to you." Id.²

² The TFO also sought Viagra, and Respondent agreed to write a prescription for the drug. Tr. 68-70. The TFO then complained of having ADD, Attention Deficit Disorder, and asked if he could try Adderall. Id. at 70-72. Respondent, however, did not prescribe the drug, telling Respondent "why don't we start with" the Percocet, the Viagra, and the Xanax. Id. at 72.

The TFO subsequently asked Respondent: “I ain’t pushing my luck, but there’s no way I could get oxycodone or Oxy?” Id. at 72. Respondent said “no” and that “it has to be medically indicated.” Id. at 72-73. Respondent’s assistant interjected that the “Percocet actually has Oxycodone in it.” Id. Respondent then stated that he would see the TFO again; the latter expressed his appreciation and that “it was worth the wait.” Id. at 73-74.

Respondent’s assistant then suggested that the TFO might be able to get oxycodone at his next visit if “it’s not quite enough.” Id. at 74. The TFO replied that he had already made his next appointment, which would be on May 4, and that he “would like to get Oxycodone.” Id. Respondent’s assistant then explained that “usually an Oxycodone visit is three hundred because that’s a higher potent narcotic” than Percocet. Id. The TFO replied that he would “pay three hundred right now if I could get it,” but Respondent’s assistant said “we’ll start with” the Percocet and that it “might do the job.” Id. According to the progress note, Respondent diagnosed the TFO as having chronic pain, right shin pain, EDD, and anxiety. Both the transcript of the visit and the progress note show that Respondent prescribed 90 Percocet and 90 Xanax. Id.; see also GX 18.

On May 4, 2010, TFO 1 again saw Respondent. GX 12. The TFO asserted that the Percocet was not helping and that Respondent had “said if it didn’t work,” he could get “something better” and asked if it was “possible” to “get OxyContin.” Id. at 24. After Respondent’s assistant listened to the TFO’s lungs, Respondent asked the TFO if he was “looking for some stronger thing than this.” Id. at 25. The TFO said he was and that he was “too big or fat.” Id.

Respondent noted that the TFO had just “started with us”; the TFO replied that he “was referred to you guys.” Id. After apparently discussing how crowded the waiting room was, the

TFO asked if he could get 80 milligram OxyContin because he had “tried some before and they, they helped big time.” Id. Respondent replied “no,” explaining that “we can do only one step at a time” because it was too “powerful [a] medicine to jump ahead several steps,” and explained that “this oxycodone is the same medication as OxyContin.” Id. The TFO then asked “[h]ow many milligrams,” and Respondent answered: “30 milligrams . . . since we’re going to give you more . . . let’s go with 180.” Id.

Respondent’s assistant then asked how much the TFO had paid at the previous visit; the TFO said “200” and added that “you said it would be an extra hundred if,” to which the assistant interjected: “yeah cause Oxycodone.” Id. at 25-26. The TFO replied that he didn’t care and asked if he could get 200 tablets. Id. at 26. Respondent’s assistant stated that 200 tablets could not be prescribed unless the TFO underwent a urine test for ten drugs, but that 180 could be prescribed without the test. Id. The TFO replied that 180 was “cool.” Id.

Next, the TFO complained about the cost of the Viagra, and ultimately said he did not need more of it. Id. at 26-27. However, the TFO then asked if he could get Xanax and asked for the two milligram tablets. Id. at 27. After Respondent’s assistant acknowledged this, the TFO stated that someone had told him about Norcos and that he didn’t “know what those are.” Id. After the assistant explained that this drug combined hydrocodone with acetaminophen, the TFO asked if he could “try those while I’m working?” Id. The assistant said “no, you’re getting 180 oxycodone.” Id. The TFO then asked if “that’s enough”; the assistant answered that “we need to see how you do on that first and then . . . graduate from there.” Id. The TFO said he was “sorry” and “didn’t know,” and Respondent replied: “Okay, that’s the Xanax and the Oxycodone.” Id. at 28.

After discussing with Respondent and his assistant how he could get Viagra for cheaper, id. at 28-29, Respondent's assistant told the TFO that "it'll be 300 for the visit" and that "we'll see you in about a month." Id. at 29. The TFO stated that he already had an appointment, thanked Respondent and his assistant, added that "you helped me out big time." Id. Consistent with the above conversation, Respondent issued the TFO prescriptions for 180 oxycodone 30mg, and 90 Xanax 2mg. GX 20. Notably, the progress note for this visit contains no indication as to how the TFO's shin pain was affecting his ability to function and how effective the medications were.

On June 1, 2010, TFO 1 made a third visit to Respondent. Respondent noted that he had seen the TFO on May 4 and asked him where he was filling his prescriptions. GX 13, at 3. Respondent's assistant took the TFO's vitals and listened to his lungs. Id. at 3-4. After a comment by Respondent, the TFO asked if he could "try something stronger than those other ones," claiming that "[t]hey don't work well" because he was "a big guy." Id. at 4. The TFO then added that he had "tried the Roxy's," and after Respondent replied that "there's no Roxy's . . . just oxycodone," the TFO asked if he could "try the other ones?" Id.

Respondent then noted that the TFO was "on 180" and "we could increase the number of tabs per day" and "do that" as "the first step," but that he didn't want to go from oxycodone to OxyContin. Id. at 4. The TFO asked if OxyContin was "no good then?" Id. Respondent answered that it was "top of the line." Id.

Respondent's assistant then suggested that the TFO's prescription be "increase[d] to 220 and then we can step up?" Id. The TFO asked how many tablets that was per day, and the assistant answered: "[a]bout 8 . . . does that work for you?" Id. The TFO asked if he "could get a

little more,” Respondent said “good” and after the TFO said he would “pay for them,” the assistant said “we’ll go to 240.” Id. at 5.

The TFO then asked what strength of Xanax he was taking; Respondent stated it was two milligrams and that this “is pretty powerful.” Id. The TFO stated that he didn’t “think so” and he “just [didn’t] feel them.” Id. Respondent replied that “most people taking 2 milligrams of Xanax” would, “in a few nights,” have to be picked up “off the floor.” Id. When the TFO replied that Respondent was “skinny and in shape” and he was “240 pounds,” Respondent stated that “most people would say the same thing” and that the drug was “very powerful.” Id.

Respondent then discussed what drugs the TFO had gotten at the previous visit, and the TFO replied that he had not gotten Viagra because it was “too much money.” Id. at 6. Respondent’s assistant then said that “[i]t’s still 300 though,” and Respondent added: “You were on Percocet, switched to oxycodone, and now we’re increasing it . . . so you’re making some pretty big steps already.” Id. The TFO expressed his appreciation, and discussed with Respondent and his assistant whether he could get more drugs “if this don’t work.” Id. Respondent’s assistant then told the TFO to schedule his next appointment for July 1st. Id. Respondent gave the TFO prescriptions for 240 oxycodone 30mg and 90 Xanax 2mg. GX 20.

Notably, the progress note for this visit now listed the TFO’s chief complaint as “more pain in lower lumbar spine,” and noted diagnoses of “chronic lbp,” i.e., lower back pain, and “chronic anxiety.” GX 18. It also indicated a finding of “tenderness L5.” Id. However, at no point in the visit did the TFO complain of lower back pain.

On June 29, 2010, TFO 1 made a fourth visit to Respondent. Upon meeting, Respondent asked the TFO “how’s that going for you?” GX 14, at 8. The TFO replied that “[i]t could be better I guess.” Id. Respondent asked the TFO if he had pain; the latter replied “yes sir.” Id. A

third person (who was not present for the previous visits) then asked “where is it?” and the TFO replied “all through here.” Id.

Following a discussion of the whereabouts of the assistant who had been at the TFO’s previous appointments, the TFO’s vital signs were taken. Id. at 9. Next, after a discussion of the TFO’s employment status, the TFO asked Respondent if he could get oxycodone instead of the Roxy’s he had previously been prescribed because the latter were “not working very well.” Id. at 11. Respondent then asked if the TFO actually wanted OxyContin as he was currently getting oxycodone; the TFO stated “that’s right,” and asked if he could try OxyContin because he thought “they would work better for [his] pain.” Id. Respondent explained that the TFO was at 220 tablets a month and would first have to go to 300 tablets and “then we’ll talk again next month.” Id. at 12. The TFO replied “okay,” and Respondent told him to “take two at a time.” Id. The TFO said he would “do whatever it takes” and asked if there was “any way” he could “get more Xanax.” Id.

Respondent then asked the TFO how he took the Xanax. The TFO stated that he took a whole one at night to help him sleep, a whole one in the morning, and that he sometimes took a third tablet if he “need[ed] it,” but “not all the time.” Id. at 13.

Next, the TFO and Respondent discussed the latter’s recommendation that he use a particular pharmacy. Id. Respondent advised the TFO that if he needed a refill, his assistant could arrange it with the pharmacy and Respondent could sign the prescription when he came back. Id. at 14. Respondent told the TFO that he was “all set then” and the TFO expressed his thanks. Id. at 14-15. Respondent issued the TFO prescriptions for 300 oxycodone 30mg and 90 Xanax 2mg. GX 20.

On August 10, 2010, TFO 1 made a final visit to Respondent. After Respondent's assistant called his name, the TFO stated that he had been there "five times," asked if he could "get Oxy 80s please, please," and offered to pay \$400 for the visit. GX 15, at 12. However, the assistant replied that "[i]t doesn't matter to me how much you pay," that he was "not going to jail just because you need something," and that he could "go somewhere else." Id. The TFO then said that he did not "want to cause problems" and asked the assistant not to "take it the wrong way." Id. The assistant replied that "it is the wrong way" and that the TFO was "on to something that is not medically ethical." Id. After the TFO insisted that "it is medical" and that he "need[ed] it," the assistant replied: "Then, you have to find it from a doctor that will prescribe it. We got the DEA looking at all the Oxy 80s like . . . prescriptions." Id. The TFO then said that he would "take the Roxies" and that he was "sorry." Id.

Respondent then told the TFO to "come on in," and upon noting that it had been "a little over a month" since his last visit, asked him if there were any "major changes." Id. The TFO said "no," but that he "was going to see if I could get the Oxy 80s," and "if not, the Roxies work fine for me." Id. at 12-13. Noting that the TFO "had oxycodone," Respondent asked him, "is that what you like?" Id. at 13. After Respondent and his assistant discussed how many pills the TFO was getting, Respondent asked the TFO if the 300 pills "works for you?" Id. The TFO replied "yes sir" and asked if his prescriptions could be sent to a pharmacy in Arizona and post-dated because the pharmacy Respondent told him to use was too "crowded." Id. Respondent and his assistant both noted that this would be illegal, and Respondent added that while he could "write a prescription right at this moment[,] today's date has to be on it." Id. Respondent then added that he could write a prescription with an instruction to the pharmacist to not fill until a

future date. Id. Respondent stated, however, that he did not know whether the Arizona pharmacy would be able to send the prescriptions out to the TFO. Id.

Respondent then asked the TFO if he would like Xanax, and the TFO asked if he could get 100 Xanax. Id. at 14. However, Respondent expressed concern that the “Xanax is so powerful” and if “they found you on the street unconscious” with his “name on the bottle in [the TFO’s] pocket,” to which the TFO replied (before Respondent finished talking) that he didn’t want Respondent “to get in trouble.” Id. Respondent then added that “we have to be very careful with it.” Id.

Respondent subsequently asked the TFO to explain what he had in mind with the prescriptions and “what we could do for you other than what we are doing here,” stating that he “didn’t quite follow with the prescriptions.” Id. Respondent’s assistant interjected that “he wants you to put, not today’s date, but a future date on the pills.” Id. When Respondent asked why, the TFO said because he “live[d] in Arizona,” and the assistant interjected that a “prescription for Class 2 narcotics are only good for two weeks” and could not be filled after that. Id. Respondent again asked the TFO why he would want that and the TFO replied “because I live in Arizona” and “she said she would ship it to me.” Id. The TFO added that he would “pay you guys for the visit or whatever” and that he “was just curious because I didn’t know how that works.” Id. After Respondent’s assistant said that doing that would be illegal, the TFO stated that he didn’t know why the pharmacist had told him that but that he thought the pharmacist “was trying to help . . . but I guess not.” Id. at 15. Shortly thereafter, Respondent left, but not before giving the TFO prescriptions for 300 oxycodone 30mg and 90 Xanax 2mg.³ Id.

³ Before he left Respondent’s office, another employee gave the TFO a slip for a ten-panel urine test, and was told “don’t forget because he won’t see you if you don’t get it” and that the test was “to make sure the drugs we give you

A second TFO made three undercover visits. The first of these occurred on June 1, 2010. After Respondent's assistant took the TFO's vitals and listened to her lungs, Respondent asked the TFO if she had pain. GX 16, at 6. The TFO responded that she had pain in her "left arm." Id. When asked how long she had the pain, the TFO stated for "several months" but then added that it was "over 6 months" and that it was related to her former work as a cocktail server. Id. Respondent then asked the TFO about her general health, whether she had ever had surgery or been admitted to the hospital, and whether she smoked or drank alcohol. Id. at 7-8.

Next, Respondent asked the TFO what medications she had been using for her pain; the TFO stated Lortab and Soma,⁴ but that the Lortab was "not really" helping. Id. at 8. Respondent then asked the TFO if she was familiar with Percocet; the TFO replied that she had heard of it but never used it. Id.

Respondent stated that "the Lortab you have tried is not quite strong enough. You need to go a step further." Id. The TFO replied "Yeah," and Respondent suggested that she "go with the Percocet" because "it's stronger." Id. Respondent then asked the TFO how often she took the Lortab when she was taking it; the TFO replied three times a day and that she took it with Soma. Id. Respondent remarked "Percocet and 90," and explained that "[i]t will be three times a day but stronger. It will be three times a day but stronger than the Lortab, okay?" Id. at 8-9.

The TFO replied "okay," and Respondent asked her if she would "also like some Soma as well then?" Id. at 9. The TFO said "yes please." Id. Respondent and his assistant then discussed

are in your system." GX 15, at 15; GX 18, at 1. However, another unidentified employee then stated that "we don't so much care about the other drugs." GX 15, at 15.

⁴ At the time of the visits, Soma (carisoprodol) was not a federally controlled substance. However, on December 12, 2011, DEA issued a final rule placing carisoprodol in schedule IV of the Controlled Substances Act. See 76 FR 77330 (2011). The final rule noted the extensive evidence of carisoprodol's abuse potential, particularly when taken in combination with narcotics.

the strength of the Percocet (10/325) and quantities he was prescribing for both drugs (90 Percocet and 60 Soma). Id.

Next, the TFO asked Respondent if he would “mind if I ask for something for stress?” Id. Respondent replied “for stress, sure,” and his assistant interjected: “just one milligram of Xanax,” and after Respondent said “yeah,” added “half a pill I think.” Id. Respondent said that he thought the TFO would “sleep better” if she was “relaxed”; the TFO replied “yes, please.” Id. Respondent then stated: “Yeah, let 30 Xanax[,] I think we can do 2 milligrams. I recommend you take half a tablet and at night, okay?” Id. The TFO replied “okay,” and after the assistant asked her to fill the prescription at a particular pharmacy, Respondent told the TFO that she could break the Xanax into 4 pieces and that she might try to take “just a quarter of a tablet and see how it works.” Id. at 10. Respondent’s assistant then told the TFO that the cost was \$200 and discussed the date of her next appointment, which was already scheduled for July 1. Id.

The progress note for this visit lists Respondent’s diagnoses as “chronic L forearm pain” but does not document the TFO’s past history. GX 19. As for Respondent’s plan, the note lists the three prescriptions which were discussed during the TFO’s meeting with Respondent and his assistant but no diagnostic testing. GX 19. The record also contains a copy of a prescription form, which is dated June 1, 2010, and which lists prescriptions for 30 Xanax 2mg, 90 Percocet 10/325mg, and 60 Soma 350mg. GX 21.

On July 2, TFO 2 returned to Respondent’s clinic. GX 17. The TFO met with Respondent’s assistant, who upon determining her name, asked: “Percocet and the uh . . . Soma? . . . Xanax?” Id. at 2. The TFO responded in the affirmative and the assistant asked: “And you paid 200?” Id. The TFO replied that she did not remember, and the assistant stated: “Yeah it’s 200.” Id. The TFO said “whatever you tell me,” the assistant told the TFO that the prescriptions

would be either phoned or faxed into the same pharmacy at which they had previously asked her to fill her prescriptions, and that it would take approximately “an hour and a half, two hours.” Id. at 3. The TFO then said that although she was “feeling better and everything,” she had run out a week earlier. Id. While the assistant declined to increase the TFO’s prescriptions, he advised her that he could fill her existing prescriptions and that they would be ready around 12:30. Id. After discussing whether she could use a different pharmacy because Respondent’s preferred pharmacy was “so busy,” the visit ended. Id.

Of note, the TFO did not see Respondent on this date, and according to the progress note for the visit, Respondent was “out of town/Las Vegas.” GX 19. The progress note states that “authorization of refill of medication has been authorized by” Respondent. Id. Other evidence shows that the TFO filled the same three prescriptions (90 Percocet 10/325mg, 30 alprazolam 2mg, and 60 carisoprodol 350mg) as she obtained at her first visit. GX 21. However, neither the transcript of the visit nor the progress note contain any evidence that Respondent’s assistant asked the TFO how the pain was affecting her ability to function.

On August 10, 2010, the TFO made a final visit to Respondent. On the progress note, Respondent listed the diagnosis as “as previous,” and issued prescriptions for the same three drugs as before but increased the TFO’s Percocet prescription to 120 tablets, adding “PRN pain/back.” GX 19; see also GX 21. However, while the Government submitted a transcript for this visit, which the TFO apparently performed at the same time as TFO 1’s visit, the transcript contains only the conversation which she had with the receptionist upon her arrival and none of the conversation which occurred during her meeting with Respondent. See GX 15.

Other Evidence

The Government also submitted a declaration of a Diversion Investigator regarding a conference call she and other law enforcement personnel did with a physician who had reviewed 200 patient files which were seized from Respondent pursuant to a search warrant in August 2010. GX 9, at 1. According to the affidavit, the physician provided his “overall impressions of [Respondent’s] prescribing habits, recordkeeping, and standard of patient care [and] stated that there is no question that [Respondent’s] standard of care fell below the civil standard for [various] reasons,” including that there were “no appropriate exams in many cases; no diagnoses were given, particularly when [Respondent] prescribed Xanax (alprazolam, Schedule IV); high doses were routinely prescribed; and doses were increased without good reason.” Id. The affidavit further stated that this physician “described these actions as flagrant and pervasive” and that he “noted that 20-year olds were frequently prescribed doses normally given to patients being treated for cancer.” Id. The affidavit then recounted “several broad areas where [the physician] felt [Respondent’s] patient treatment was lacking.” Id. at 2.

In Richardson v. Perales, 402 U.S. 389 (1971), the Supreme Court held that a physician’s written report could constitute substantial evidence notwithstanding that it was hearsay. Notably, among the factors the Court found significant was that “[c]ourts have recognized the reliability and probative worth of written medical reports even in formal trials and, while acknowledging their hearsay character, have admitted them as an exception to the hearsay rule.” 402 U.S. at 405.

There is, however, no similar tradition of courts holding affidavits relating the substance of telephone interviews of physicians to be inherently reliable. Thus, the DI’s affidavit stands on a fundamentally different footing than that of a physician’s written report. It is, however, unnecessary to decide whether the doctor’s opinions, as related in this affidavit, can constitute

substantial evidence, notwithstanding that they are hearsay within hearsay, because they are simply generalities regarding his review of some 200 files.⁵

Moreover, the legitimacy of Respondent's prescribing to these 200 patients is not before the Agency. Rather, the Government has submitted evidence regarding Respondent's prescribing to the two TFOs. While in its Request for Final Agency Action, the Government asserts that the physician reviewed the files of the two TFOs, nothing in the DI's affidavit (or any other exhibit) establishes this as a fact. Nor does anything in the affidavit reflect that the physician offered opinions specific to the prescriptions Respondent issued to the TFOs. In short, this affidavit has no probative value in determining whether Respondent violated federal law in issuing prescriptions to the TFOs.

DISCUSSION

Section 304(a) of the Controlled Substances Act provides that a "registration pursuant to section 823 of this title to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). In determining the public interest, Congress directed that the following factors be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing . . . controlled substances.

⁵ As another example of why this evidence is properly given no weight, according to the affidavit, the physician stated that "there is no documented reason for the Xanax/oxycodone combination" and the physician explained "that these two drugs build on each other, and can easily leave a patient over-sedated, which can lead to an overdose." GX 8, at 2. It is, however, unclear whether the physician was referring to a general lack of documentation in the patient charts for prescribing these drugs in combination or whether he was maintaining that drugs could never be safely prescribed together. Id.

- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). In addition, pursuant to 21 U.S.C. 824(d), "[t]he Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to public health or safety."

The public interest factors are considered in the disjunctive. Robert A. Leslie, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application for a registration. Id. Moreover, I am "not required to make findings as to all of the factors." Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); see also MacKay v. DEA, 664 F.3d 808, 816 (10th Cir. 2011); Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

The Government has "the burden of proving that the requirements for . . . revocation or suspension pursuant to section 304(a) . . . are satisfied." 21 CFR 1301.44(e); see also 21 CFR 1301.44(d) (Government has "the burden of proving that the requirements for . . . registration pursuant to section 303 . . . are not satisfied"). As no DEA regulation provides that the consequence of waiving a hearing is a default, the Government must therefore support its proposed action with substantial evidence.

Having considered all of the factors, I conclude that the Government's evidence pertinent to factors two (Respondent's experience in dispensing controlled substances) and four (Respondent's compliance with applicable laws related to controlled substances), establishes that

Respondent has committed acts which render his registration “inconsistent with the public interest.” 21 U.S.C. 824(a)(4).⁶

Factors Two and Four – Respondent’s Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Under a longstanding DEA regulation, to be effective, “[a] prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a). As the Supreme Court has explained, “the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” Gonzales v. Oregon, 546 U.S. 243, 274 (2006) (citing United States v. Moore, 423 U.S. 122, 135, 143 (1975)).

Under the CSA, it is fundamental that a practitioner must establish and maintain a bonafide doctor-patient relationship in order to act “in the usual course of . . . professional practice” and to issue a prescription for a “legitimate medical purpose.” Laurence T. McKinney, 73 FR 43260, 43265 n.22 (2008); see also Moore, 423 U.S. at 142-43 (noting that evidence established that physician “exceeded the bounds of ‘professional practice,’” when “he gave inadequate physical examinations or none at all,” “ignored the results of the tests he did make,”

⁶ The record contains no evidence regarding the recommendation of the state licensing board or professional disciplinary authority. See 21 U.S.C. 823(f)(1). While possession of state authority to dispense controlled substances is a statutory requirement for holding a DEA practitioner’s registration, see id. 802(21), this factor does not support a finding either for, or against, the continuation of Respondent’s registration. See Joseph Gaudio, 74 FR 10083, 10090 n.25 (2009); Mortimer B. Levin, 55 FR 8209, 8210 (1990).

There is also no evidence in the record that Respondent has been convicted of an offense related to the manufacture, distribution or dispensing of controlled substances. See 21 U.S.C. 823(f)(3). While this factor supports the continuation of Respondent’s registration, DEA has long held that this factor is not dispositive. See, e.g., Edmund Chein, 72 FR 6580, 6593 n.22 (2007).

and “took no precautions against . . . misuse and diversion”). The CSA, however, generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. See Kamir Garces-Mejias, 72 FR 54931, 54935 (2007); United Prescription Services, Inc., 72 FR 50397, 50407 (2007).

By regulation, the Nevada State Board of Medical Examiners has adopted by reference the Federation of State Medical Boards of the United States, Inc.’s, 2004 Model Policy For The Use of Controlled Substances For The Treatment of Pain. See Nev. Admin. Code 630.187.

According to the Preamble of the 2004 Policy,

[t]he Board will consider prescribing, ordering, dispensing, or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state and federal law is required.

Model Policy, I.

Section II of the Model Policy governs the evaluation of patients. This provision states:

A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should document the presence of one or more recognized medical indications for the use of a controlled substance.

Model Policy, II.

The Model Policy also provides that “[t]he written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned.” Id. Moreover, “[t]he physician should discuss the risks and benefits of

the use of controlled substances with the patient.” Id. II. In addition, the Policy provides that “[t]he physician should keep accurate and complete records to include” the following:

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements, and
10. periodic reviews.

Id.

Finally, under a Nevada Board regulation, “[a] person who is licensed as a physician . . . shall not . . . [e]ngage in the practice of writing prescriptions for controlled substances to treat acute pain or chronic pain in a manner that deviates from the guidelines.” Nev. Admin. Code 630.230(1)(l).

TFO 1’s Prescriptions

As found above, at TFO 1’s first visit, Respondent prescribed to him both Percocet 10 and Xanax. At this visit, the TFO unequivocally complained of pain even if he stated that it occurred only when he ran. Moreover, Respondent’s assistant clearly performed a physical examination, and while the Government asserts that this was “a cursory examination,” Req. for Final Agency Action at 4, it offered nothing bordering on substantial evidence to support this contention.

However, even if Respondent’s evaluation of TFO 1 was sufficient to support his prescribing of Percocet, other evidence establishes that Respondent was not engaged in the legitimate practice of medicine but was dealing drugs. More specifically, Respondent, without solicitation by the TFO, asked him if there was any other medication he took for anxiety or

Xanax. While the TFO replied he was “always stressed” but was not currently taking anything, Respondent made no effort to determine the extent of the TFO’s symptoms and whether they warranted a diagnosis of anxiety. Moreover, when Respondent’s assistant asked the TFO if Xanax helped him, the TFO replied, laughing no less, that “everything helps. Can I get some Xanax?” Respondent then said “yeah, but that’s why he mentioned it. We’d be happy to write some Xanax for you, if you liked it then.”

Expert testimony is unnecessary to determine that controlled substances are not prescribed because patients like them, but rather to treat a legitimate medical condition. I therefore conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Xanax to TFO 1, and therefore violated 21 CFR 1306.04(a).

Moreover, at various points in this visit, TFO 1 provided additional indication that he was a drug-seeking patient as he sought various other controlled substances such as testosterone cream and Adderall. In addition, even after Respondent had agreed to write a Percocet prescription (which contains oxycodone) for him, the TFO asked if he was pushing his luck but then said he would like to get oxycodone or Oxy. While Respondent said “no,” and that “it has to be medically indicated,” his assistant then suggested that he might be able to get it at his next visit if the Percocet was “not quite enough.”

Following this, the TFO stated he had already made his next appointment and added that he “would like to get oxycodone” at it. Respondent’s assistant then advised the TFO that the fee would be \$300 rather than \$200 for an oxycodone visit because the drug was more potent than Percocet and the TFO offered to pay \$300 “right now if [he] could get” oxycodone. Thus, the TFO provide ample indication that he was a drug-seeking patient. Moreover, the statement of

Respondent's assistant begs the question of why Respondent's charge would be \$100 more if a stronger narcotic was prescribed.

At TFO 1's second visit, the TFO sought "something better" and asked if he could get OxyContin 80mg, which he claimed to have "tried . . . before" and that "they helped big time." While Respondent said "no," the TFO's comment did not prompt any questioning as to his source for the OxyContin. And while the TFO claimed that the Percocet was not helping, neither the transcript of the visit nor the progress note for it indicate that Respondent asked the TFO about "the nature and intensity of the pain" and its effect "on [his] physical and psychological function" as mandated by the Nevada rule.

Nonetheless, Respondent offered to prescribe oxycodone 30mg, a drug three times more potent than the Percocet the TFO had previously obtained. Moreover, he then prescribed 180 pills, thus giving the TFO a prescription for six times the amount of oxycodone he had prescribed at the previous visit. In addition, as further evidence of the TFO's drug seeking behavior, he then asked for more Xanax and if he could try some Norco, the latter being a schedule III narcotic combining hydrocodone with acetaminophen. While Respondent did not prescribe Norco (because the TFO was already getting 180 oxycodone 30mg), he did prescribe another 90 Xanax 2mg to the TFO.

I conclude that both the oxycodone 30mg and Xanax prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. As for the oxycodone, even if Respondent's initial prescription for Percocet was medically justified, there was no justification for a six-fold increase in the amount of oxycodone that he prescribed.⁷

⁷ Buttrressing this conclusion is the discussion the TFO had with Respondent's assistant as to how many tablets he could obtain without undergoing a urine test. It is difficult to understand why 180 tablets would not trigger such a test but 20 additional tablets would.

Likewise, the transcript of the visit indicated that the TFO simply asked for more Xanax and that there was no discussion as to whether he had any symptoms which warranted the prescription.

At TFO 1's third visit, he once again sought "something stronger" than oxycodone 30mg, claiming they didn't "work well." While Respondent stated that he did not want to go from oxycodone to OxyContin, because the latter was "top of the line," Respondent increased the TFO's prescription, this time to 240 tablets of oxycodone 30mg. Here again, there was no discussion of the nature and intensity of the TFO's pain and how it was affecting his ability to function. Nor, notwithstanding that the previous prescription represented a six-fold increase in dosage, was there any discussion (other than the TFO's assertion that the drug did not "work well") as to the effectiveness of the previous prescription. Finally, Respondent wrote in the progress note a new and different diagnosis of chronic lower back pain even though there is no indication in the transcript of the visit that the TFO complained of having any back pain. Accordingly, I find that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in issuing the oxycodone prescription. 21 CFR 1306.04(a).

Moreover, in discussing the Xanax prescription, the TFO disagreed with Respondent's statement that the strength he was taking was "pretty powerful" and added that he "just [didn't] feel them." Once again, there was no discussion of any symptoms the TFO had which would warrant the prescribing of Xanax. Accordingly, I conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Xanax to the TFO. 21 CFR 1306.04(a).

At his fourth visit, TFO 1 again complained that the oxycodone was "not working very well" and Respondent asked if he actually wanted OxyContin. While the TFO replied that he thought that OxyContin "would work better for [his] pain," once again the transcript of the visit

shows that Respondent made no inquiry as to the nature and intensity of the TFO's pain and its effect on his ability to function. While Respondent did not prescribe OxyContin (because the TFO "would first have to go to 300 tablets" of oxycodone 30mg), he nonetheless increased his oxycodone prescription to 300 tablets and the TFO told him that he would "do whatever it takes" to get OxyContin. Thus, I conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing oxycodone to the TFO.

At his final visit, TFO 1 again asked if he could get OxyContin and offered to pay \$400 for the visit. Manifesting his awareness that the TFO was not a legitimate pain patient but was engaged in drug-seeking, Respondent's assistant replied that "[i]t doesn't matter to me how much you pay" and that he was "not going to jail just because you need something." Moreover, while Respondent asked the TFO if there had been any "major changes" since his last visit, the TFO said no but that he "was going to see if I could get the Oxys 80," but "if not, the Roxies work fine for me." After noting that the TFO had been getting oxycodone (the same drug as Roxicodone), Respondent asked the TFO, "is that what you would like?" and whether 300 pills "works for you?"

Notably, at no point did the TFO complain of pain, and other than Respondent's question whether there had been any "major changes" since his last visit, neither Respondent nor his assistant questioned the TFO about the nature and intensity of his pain, and its effect on his ability to function. Moreover, Respondent then asked the TFO if he would like Xanax and the TFO asked if he could get 100 tablets. Manifesting that he knew the TFO was a drug abuser, Respondent expressed his concern that he could get in trouble because the "Xanax is so powerful" if "they found [the TFO] on the street unconscious" with Respondent's name on the bottle in his pocket. Notwithstanding that there was no legitimate purpose for either prescription,

Respondent prescribed 300 oxycodone 30mg and 90 Xanax 2mg to the TFO, in violation of 21 CFR 1306.04(a).

TFO 2's Prescriptions

As found above, at TFO 2's first visit, she represented that she had pain in her left arm, that the pain was related to her former work as a cocktail waitress, and that she had had the pain for over six months. However, Respondent made no further inquiry into whether the TFO had suffered an injury, the nature and intensity of her pain, its effect on her physical and psychological function, and whether she had previously been treated for it. Moreover, while the TFO stated that she had used Lortab and Soma for her pain, Respondent made no inquiry as to the TFO's source for these drugs. Furthermore, the TFO then asked Respondent if he would mind if she "ask[ed] for something for stress?" While Respondent stated that he thought the TFO would "sleep better" if she was relaxed, he conducted no inquiry into what symptoms the TFO had that would warrant prescribing Xanax. Respondent then prescribed 90 Percocet 10/325, 30 Xanax 2mg, as well as Soma. Based on Respondent's clear lack of compliance with the Nevada Board's Policy, I conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing Percocet and Xanax to the TFO.

Moreover, at her second visit, Respondent was not present and the TFO was seen by his assistant, who either called or faxed in prescriptions for 90 Percocet and 30 Xanax. While the TFO had stated that she was "feeling better and everything," Respondent's assistant conducted no inquiry into the nature and intensity of her pain and its effect on her physical and psychological functioning. Nor did Respondent's assistant discuss with the TFO her use of Xanax and whether she even needed a refill. As noted above, while Respondent was not present

at his clinic, the TFO's chart noted that he authorized the prescriptions. Accordingly, I conclude that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice in authorizing the prescriptions for Percocet and Xanax and therefore violated 21 CFR 1306.04(a).⁸

Based on the numerous controlled substance prescriptions which Respondent issued in violation of 21 CFR 1306.04(a), I conclude that the evidence relevant to factors two and four supports a finding that he has "committed such acts as would render his registration . . . inconsistent with the public interest." 21 U.S.C. 824(a)(4). I further conclude that Respondent's conduct is sufficiently egregious as to warrant the revocation of his registration and the denial of his application to renew his registration. Accordingly, I will order that Respondent's registration be revoked and that his pending application be denied.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BW5180372, issued to Henri Wetselaar, M.D., be, and it hereby is, revoked. I further order that any pending application of Henri Wetselaar, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effective immediately.⁹

Dated: August 31, 2012

Michele M. Leonhart
Administrator

⁸ Because there is no evidence establishing the substance of what actually occurred during the TFO's third visit with Respondent (other than that she received more prescriptions), I conclude that there is no basis to conclude that these prescriptions also violated federal law.

⁹ Based on the allegations that led me to order the Immediate Suspension of Respondent's registration, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67

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